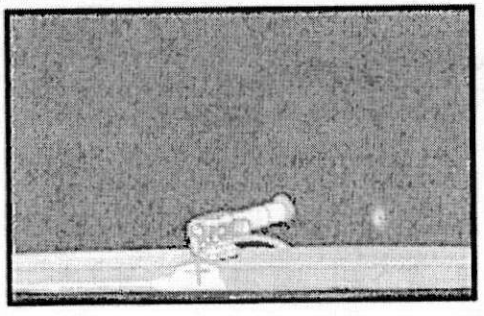
K120261

MAY - 2 2012

PEROUSE MEDICAL

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
As required by section 807.92(c)

Submitter	PEROUSE MEDICAL - Route du Manoir - 60173 IVRY LE TEMPLE - FRANCE Phone +33(0)3 44 08 17 00 Fax +33(0)3 44 08 17 01 Website: www.perousemedical.com
Contacts	Marie-Noëlle EROUT – Quality & Regulatory Affairs Director – e-mail : m-n.erout@perousemedical.com
Preparation date	December 16th 2011
Trade Name	PPS PI® Pressure Injectable Safety Huber Needle
Common Name	Intravascular administration set
Classification Name	set, administration, intravascular
Legally marketed predicate devices	- Power Loc safety infusion set, Bard access systems (510(k) n° K082306). The indications for use are the same as the PPS PI® Pressure Injectable Safety Huber Needle - Polyperf Safe (510(k) n°K063631). The indications for use are the same than PPS PI® Pressure Injectable Safety Huber Needle without the pressure injection ability.
Description	The PPS PI® Pressure Injectable Safety Huber Needle is a curved safety Huber needle mounted with one connection line ideal for accessing pressure injectable ports. This device allows pressure injection of contrast media during CT (computerized tomography) scans or MRI (magnetic Resonance imaging) and is MR Conditional. The PPS PI® curved Huber needle is available in various lengths and diameters; with or without a lateral injection site. Luer-Lock connectors, are provided, on which closed protective caps are screwed (end of the main line and of the Y site) which must not be used as sealing caps .One clamp is also provided (2 clamps for references with "Y" site) PPS PI® Pressure Injectable Safety Huber Needle is single use Safety removal of the PPS PI® Pressure Injectable Safety Huber Needle:  ***STEP 1:*** Usual use position (horizontal plunger).

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SAS au capital de 131 670 euros
SIREN 317 883 999 RCS
N° TVA intracommunautaire
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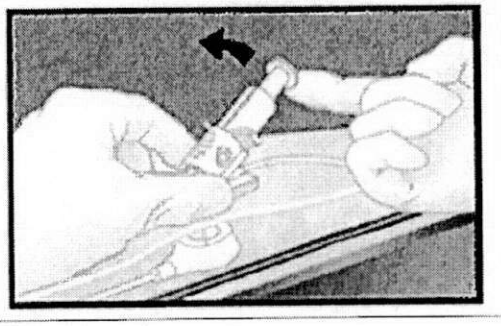
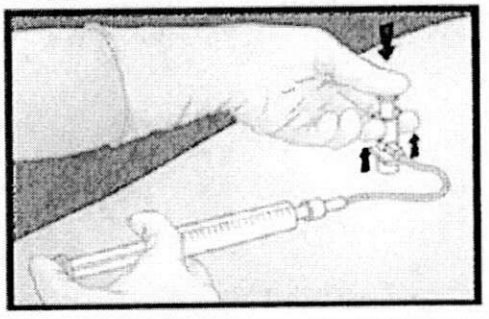
		***STEP 2: Preparation***: Tilt the plunger from the horizontal position to a vertical position.
		***STEP 3:*** Using your thumb, lower the plunger to bring it in contact with the skin. Lift the extractor (bottom to top motion) until the complete locking of the needle: you should hear a "CLICK" sound.
Intended Use	The PPS PI® curved safety Huber needle is indicated for: - Administration or withdrawal of fluids through implanted ports. - Pressure injection of contrast media into the central venous system only with an implantable infusion port that is also indicated for pressure injection. -The maximum recommended infusion rate at 11,8 cPs is : - 5mL/sec. for 19Ga. needle -5 mL/sec. for 20 Ga. needle - 2 mL/sec. for 22 Ga. needle. - The PPS PI® Curved Safety Huber needle is indicated to PPS PI® Curved Safety Huber needle does not protect against other routes of blood-borne pathogen transmission.	
Performance data	Performance data included with this submission ✓ Biocompatibility ✓ Safety and functionality testing	
Substantial equivalence	PPS PI® Pressure Injectable Safety Huber Needle connecting lines are substantially equivalent to: - Bard Power Loc predicate device in term of intended use and technological characteristics (materials, design and functionality). - POLYPERF Safe predicate device except for the pressure injection of contrast media	
Conclusion	Performance data demonstrate safety, effectiveness and substantial equivalence	

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Isabelle Jeanty
Deputy General Manager & Quality & Regulatory Affairs Director
Perouse Medical
Route Du Manoir
60173 Ivry Le Temple
France

MAY - 2 2012

Re: K120261
Trade/Device Name: PPS PI® Pressure Injectable Safety Huber Needle
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FPA, FMI
Dated: March 12, 2012
Received: March 13, 2012

Dear Ms. Jeanty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K120261

Device Name: PPS PI® Pressure Injectable Safety Huber Needle

Indications for Use:

The PPS PI® curved safety Huber needle is indicated for:

- Administration or withdrawal of fluids through implanted ports.
- Pressure injection of contrast media into the central venous system only with an implantable infusion port that is also indicated for pressure injection.
- The maximum recommended infusion rate at 11,8 cP is :
  - 5 mL/sec. for 19 Ga. needle
  - 5 mL/sec. for 20 Ga. needle
  - 2 mL/sec. for 22 Ga. needle.
- The PPS PI® Curved Safety Huber needle is indicated to prevent blood-borne pathogen exposures caused by accidental needle punctures. The PPS PI® Curved Safety Huber needle does not protect against other routes of blood-borne pathogen transmission.

5/1/2012

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120261

Prescription Use ✓	AND/	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)	OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)